

1982 and on or before May 9, 1988, complied with the 1981 edition of the Life Safety Code, is considered to be in compliance with this standard as long as the RPCH continues to remain in compliance with that edition of the Code. The 1967 and 1981 Life Safety Codes are available for inspection at the HCFA Information Resource Center, 6325 Security Boulevard, Room G-10-A East High Rise Building, Baltimore, MD 21207.

(3) After consideration of State survey agency findings, HCFA may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the RPCH, but only if the waiver does not adversely affect the health and safety of patients.

(4) The RPCH maintains written evidence of regular inspection and approval by State or local fire control agencies.

**§ 485.627 Condition of participation: Organizational structure.**

(a) *Standard: Governing body or responsible individual.* The RPCH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the RPCH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

(b) *Standard: Disclosure.* The RPCH discloses the names and addresses of—

(1) Its owners, or those with a controlling interest in the RPCH or in any subcontractor in which the RPCH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter;

(2) The person principally responsible for the operation of the RPCH; and

(3) The person responsible for medical direction.

**§ 485.631 Condition of participation: Staffing and staff responsibilities.**

(a) *Standard: Staffing*—(1) The RPCH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants,

nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the RPCH.

(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the RPCH operates.

(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the RPCH has one or more inpatients.

(b) *Standard: Responsibilities of the doctor of medicine or osteopathy.* (1) The doctor of medicine or osteopathy—

(i) Provides medical direction for the RPCH's health care activities and consultation for, and medical supervision of, the health care staff;

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the RPCH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the RPCH's patient records, provides medical orders, and provides medical care services to the patients of the RPCH; and

(iv) Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the RPCH. A site visit is not required if no patients have been treated since the latest site visit.

(c) *Standard: Physician assistant, nurse practitioner, and clinical nurse specialist*

*responsibilities.* (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the RPCH's staff—

(i) Participate in the development, execution and periodic review of the written policies governing the services the RPCH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the RPCH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the RPCH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(3) Whenever a patient is admitted to the RPCH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the RPCH is notified of the admission.

**§ 485.635 Condition of participation: Provision of services.**

(a) *Standard: Patient care policies.* (1) The RPCH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.631(a)(1); at least one member is not a member of the RPCH staff.

(3) The policies include the following: (i) A description of the services the RPCH furnishes directly and those furnished through agreement or arrangement.

(ii) Policies and procedures for emergency medical services.

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical

consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the RPCH.

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

(vii) If the RPCH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of § 483.25(i) is met with respect to inpatients receiving posthospital SNF care.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the RPCH.

(b) *Standard: Direct services.*—(1) *General.* The RPCH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory services.* The RPCH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a).